In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-171V

(to be published)

* *	Chief Special Master Corcoran
C.N., by his mother and natural guardian, PHUONG DINH, *	
*	Filed: February 14, 2022
Petitioner, *	
v. *	
*	
SECRETARY OF HEALTH AND HUMAN SERVICES, *	
*	
Respondent. *	
*	
* *	

Renee J. Gentry, Vaccine Injury Clinic, George Washington Univ. Law School, Washington, DC, for Petitioner.

Sarah B. Rifkin, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On February 4, 2016, Phuong Dinh filed a petition for compensation under the National Vaccine and Injury Compensation Program (the "Vaccine Program").[2] (ECF No. 1) ("Pet."). Petitioner alleged that her child, C.N., developed chronic eczema, also called atopic dermatitis ("AD"), as a result of vaccines he received on May 29 and June 26, 2013, when he was approximately two to three months old. Pet. at 1.

[1] This Decision shall be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to Section 300aa of the Act (but will omit the statutory prefix).

I have determined the matter could best be resolved via ruling on the record. Now, based on review of the medical records and expert reports submitted by each side, I deny an entitlement award. C.N.'s medical history suggests his AD preceded the relevant vaccinations, and insufficient evidence has been offered to prove that any symptoms experienced thereafter were more than temporally associated.

I. Medical History

Birth and Early History

C.N. (Petitioner's fourth child) was born on March 29, 2013, and had a normal newborn screening. Ex. 7 at 4, 26. His skin was described as "well-perfused, warm and dry; brisk capillary refill; no rashes or lesions noted." Ex. 5 at 12. At a one-month check-up, on April 30, 2013, C.N. was deemed to be healthy, although he experienced frequent spit-ups that were noted as evidence of possible reflux. Ex. 7 at 25.

Vaccinations and First Clinical Indicia of Dermatitis

C.N. had his two-month checkup on May 29, 2013. Ex. 7 at 24. At this point, his pediatrician noticed "dry cheeks + scalp" and "eczema—vaseline" under "assessment"—and thus some kind of eczema was present even before C.N. received any of the vaccines at issue. *Id.* C.N. received the HiB, Prevnar 13, and Rotarix vaccines[3] that day as well. *Id.* at 6. Petitioner has alleged that the night of May 29th, C.N. was unable to sleep, had a fever, and was crying. Ex. 19 at 4. Then, two days after (May 31, 2013) he allegedly developed red spots on his face and his skin became dry, later becoming itchy, although it gradually improved by June 2013. *Id.*

There is a several-week gap in the treatment history filed in this case, with no evidence that Petitioner sought treatment for C.N. due to rash or skin concerns. Then, on June 26, 2013, C.N. returned to his pediatrician and received his four-month-old vaccines—including Pediarix, a combination of Hepatitis B, Diphtheria, Tetanus, Pertussis, and polio vaccines. Ex. 7 at 6. The concerns Petitioner has included in her fact affidavit about a reaction to the May 2013 vaccinations are not memorialized in this particular record, although it does contain notes observing the presence of "red scaly dry cheeks + scalp." *Id.* at 23.

[3] The HiB vaccine is the Haemophilus influenza type B vaccine usually given at a child's two-month vaccination. *Hib VIS*, CENTER FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/vaccines/hcp/vis/vis-statements/hib html (last visited Jan. 11, 2022). The Prevnar 13 vaccine is the "pneumococcal 13-valent Conjugate Vaccine" that is an "[a]ctive immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in children 6 weeks through 5 years of age." *Prevnar 13*, FDA, https://www.fda.gov/vaccines-blood-biologics/vaccines/prevnar-13 (last visited Jan. 11, 2022). Rotavirus vaccines are "an oral solution containing a live, attenuated human rotavirus strain; active against serotypes G1, G3, G4, and G9." *Rotavirus* vaccines, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=119634 (last visited Jan. 11, 2022).

Petitioner alleges that (as with the May vaccinations) on the night of the June vaccinations C.N. experienced a fever reaching 102 °F, cried the entire night, and resisted drinking his formula. Ex 19 at 5. She adds that the following day (June 27, 2013), C.N. did not smile or make eye contact, developing red spots on his face, arms, legs, and body. *Id.* These then turned into big reddish-purple patches over his body and he "continued to refuse his formula and would cry often, especially after he woke up from his short naps." *Id.* There are no contemporaneous medical records confirming these contentions, however.

Dermatitis Diagnosis and Efforts at Treatment

C.N.'s next visit to his pediatrician was on July 15, 2013, with concerns of continued "red dry cheeks w/ scaly dry scalp." Ex. 7 at 22. At that visit C.N. was diagnosed with moderate to severe atopic dermatitis. *Id.* A week later, on July 22, 2013, Dr. Tung Duc Nguyen, a pediatrician, made notes of C.N. having scaly patches on his skin and "yellow crusted patches" on his scalp. Ex. 9 at 3. C.N. was subsequently diagnosed with a cow milk protein allergy, with his AD exacerbation noted (along with some reflux), and he was referred to a children's hospital allergist and dermatologist for further work-up. Ex. 7 at 20, 21.

Dr. Lan Tu saw C.N. at Potomac Medical Center on August 19, 2013, with the chief complaint of a "[b]ody rash, sticky eyes. Itching skin." Ex. 10 at 1. There were notes of "onset of intermittent body skin itching, aggravated by dry weather." *Id.* Examination revealed "scattered erythematous, maculopapular lesions scattered all over body, with some excoriations noted, some urticaria." *Id.* at 2. C.N. was diagnosed with dermatitis likely attributable to "recent onset of intermittent body skin itching, aggravated by dry weather." *Id.* at 3. The recommendation was for C.N. to "avoid strong soaps and cleaners, some perfumes and makeup, substances such as chlorine (as in swimming pool), mineral oil, or solvents, dust and cigarette smoke" along with using "enough lubricants after bath" and "avoid long or hot baths and showers." *Id.* Two days later (August 21, 2013), C.N. returned for an allergy skin test and the finding was of dermatitis, with "scattered erythematous, maculopapular lesions scattered all over body, with some excoriations noted, some urticaria." *Id.* at 4.

C.N. went to visit Nurse Practitioner Laura Noonan on August 22, 2013, and August 28, 2013. Ex. 17 at 3–4. At that point his condition had improved, and he was eating better after his formula version had been changed. *Id.* C.N.'s labs showed "very elevated absolute eosinophil counts, elevated RAST to peanut, egg, and wheat. Negative to corn, milk, and soy," and a normal hypereosinophilia panel. *Id.* He was again diagnosed with AD plus eosinophilia.[4] *Id.*

[4] Eosinophilia is "the formation and accumulation of an abnormally large number of eosinophils in the blood." *Eosinophilia*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=16719&searchterm=eosinophilia (last visited Jan. 12, 2022).

In September 2013, C.N. was taken to a dermatologist, who observed the existence of a full body rash and provided treatment instructions for additional topical ointments plus medications (including antibiotics and antihistamines). Ex. 11 at 4–5. C.N. also saw NP Noonan again that same month. Ex. 17 at 2. His eczema has worsened, and the rash at this time was patchy and very irritated, with erythema and popular rash on bilateral cheeks and around his eyes. *Id.* The rash and associated dermatitis continued on into that fall, despite treatment efforts. Ex. 7 at 16; Ex. 12 at 17. At an October 24, 2013 doctor's visit, exam revealed "worsening red dry skin lesions on ext x 4 and lower back." Ex. 7 at 16.

Worsening of Condition into 2014

Despite Petitioner's best efforts, C.N.'s condition remained resistant to treatment, and by March 2014 he was hospitalized for severe eczema and fever. Ex. 7 at 50. His physical examination noted the presence of "diffuse disseminated eczematous rash surrounded by multiple uniform and crusted vesicles." *Id.* at 52. C.N. was now diagnosed with eczema herpeticum after he tested positive for HSV 1.[5] Ex. 5 at 103. On his second day of hospitalization, C.N.'s skin lesions had improved without any new outbreaks. Ex. 7 at 52. The following month, on April 2, 2014, C.N. was noted as having improved slightly, but with continued flare-ups. Ex. 8 at 3. At an appointment with NP Noonan, he displayed on exam two to three "very swollen and inflamed patches on his right forearm." *Id.*

C.N.'s AD persisted into 2015, with his family even trying to go to Vietnam in February 2015 to see if the condition would improve. Ex. 7 at 9; Ex. 19 at 8. C.N. was referred to an allergist and dermatologist in April 2015. Ex. 7 at 7. A different dermatologist who saw him on May 13, 2015, recorded dermatitis on his face and body, eczematous inflammation characterized, and he was not using medication, so he was prescribed additional treatments. Ex. 14 at 1, 3. The records filed in this case reveal that continuing into 2016, C.N. was still displaying "red swollen wet eczema lesions," with cellulitis and eczema. Ex. 18 at 8. Homeopathic remedies have also been attempted. Ex. 20.

II. Expert Reports

A. *Joseph Bellanti, M.D.*

Dr. Bellanti filed four expert reports on behalf of C.N. Report, dated April 12, 2017, filed as Ex. 22 (ECF No. 34-2) ("First Bellanti Rep."); Report, dated November 8, 2017, filed as Ex. 28

[5] HSV 1, also called human herpes simplex virus, often causes cold sores and "is an etiologic agent of herpes simplex and causes predominantly nongenital infections…. The virus can pass along nerves and remain latent in ganglia, from which it may be reactivated." *Human Herpesvirus 1*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=80846 (last visited Jan. 12, 2022).

(ECF No. 43-2) ("Second Bellanti Rep."); Report, dated May 17, 2018, filed as Ex. 33 (ECF No. 52-2) ("Third Bellanti Rep."); Report, dated March 6, 2019, filed as Ex. 35 (ECF No. 61-2) ("Fourth Bellanti Rep."). Dr. Bellanti opines that the vaccines C.N. received in May–June 2013 caused his AD.

Dr. Bellanti is a board-certified physician. Ex. 23, dated February 3, 2013, at 4 (ECF No. 34-3) ("Bellanti CV"). He currents works as a Professor of Pediatrics and Microbiology-Immunology at the Georgetown University School of Medicine, and is the Director at the International Center for Interdisciplinary Studies of Immunology at Georgetown University. Bellanti CV at 1. Dr. Bellanti also works as a Pediatrician at the Georgetown University Hospital; at the Children's Hospital National Medical Center as an Academic Staff in Pediatrics; at the Virginia Hospital Center in the Department of Pediatrics; at the INOVA Fairfax Hospital in the Department of Pediatrics; and as the Medical Director of SmarTravel International Health and Advanced Health Resources, L.L.C. *Id.*

Dr. Bellanti attended the University of Buffalo for undergraduate and medical school. Bellanti CV at 3. He then did a residency in Pediatrics at the Children's Hospital of Buffalo. *Id.* He continued on with a Special NIH Trainee in Immunology at the J. Hillis Miller Health Center at the University of Florida and was a Research Virologist at the Walter Reed Army Institute of Research. *Id.* Dr. Bellanti has given multiple international lectures in immunology. *Id.* at 9–11. He has also published numerous articles, abstracts, and books/book chapters on the immune response, pediatrics, and vaccines. *Id.* at 12–46.

First Report

Dr. Bellanti's first report (three pages in substantive length, and hence somewhat summary in nature) described the series of vaccines that C.N. received in May–June 2013, noting the symptoms Petitioner alleges were experienced immediately thereafter. First Bellanti Rep. at 2. He then proposed several possible mechanisms of how the vaccines could in combination cause C.N.'s eczema. *Id.*

Although the majority of those who get vaccinated do not experience adverse reactions, Dr. Bellanti noted, some patients do—likely in part because of their genetics and immune status. First Bellanti Rep. at 2. Vaccination in that kind of susceptible individual can result in pathology. In particular, he maintained, vaccines "can result in immune dysregulation and inflammation" through their contents, causing "an abnormal alteration of macrophage function, and inflammatory reactions (i.e. atopic dermatitis)." *Id.* at 3.

Dr. Bellanti's causation theory was rooted in the nature of AD. As he explained, "[s]everal cofactors" are relevant to AD's course, and he listed impairment of the skin barrier, immune

system issues, and genetic background as all relevant. First Bellanti Rep. at 2. Macrophages (a kind of immune cell)[6] are pivotal to this process at a cellular level, since they can accumulate acutely in inflamed skin. *Id.* at 3; S. Kasraie & T. Werfel, *Role of Macrophages in the Pathogenesis of Atopic Dermatitis,* 13 Mediators of Inflammation 1 (2013), filed as Ex. 24 (ECF No. 35-2) ("Kasraie & Werfel"). Although in the early stages of an inflammatory process these macrophages can help resolve inflammation, the persistence of it and accompanying "altered function of macrophages" can lead to chronic inflammatory diseases like AD. First Bellanti Rep. at 3.

Kasraie & Werfel does not say anything about how *vaccination* might cause aberrant macrophage activity in association with AD's pathogenesis. But Dr. Bellanti attempted to connect the two with other evidence. Vaccines, he explained, are multi-ingredient preparations, often containing adjuvants such as "cationic aluminum compounds and virus-like particles (VLPs)." First Bellanti Rep. at 2. One recent study observed (via electron-microscope) the presence of solid contaminants (identified in other literature to be non-biodegradable and non-biocompatible) left after vaccination. *Id.* at 3; A. Gatti & S. Montanari, *New Quality-Control Investigations on Vaccines: Micro- and Nanocontamination,* 4 Int. J. Vaccin. & Vaccination 72 (2017), filed as Ex. 25 (ECF No. 35-3) ("Gatti & Montanari"). Gatti & Montanari evaluated 44 vaccines administered in Italy and France through an in vitro/laboratory test, and revealed the presence of a variety of compounds or metallic elements left after vaccination but not identified in the vaccine package inserts as components. Gatti & Montanari at 75. These unexpected foreign bodies had the capability to induce inflammatory responses (although the study did not specifically analyze that capacity), and the study's authors urged better manufacturing quality control to limit the problem. *Id.* at 85.

More specifically, Dr. Bellanti maintained that "intracytoplasmic inclusions" consistent with aluminum hydroxide (commonly used as a vaccine adjuvant to spur the immune response) had been detected in macrophages of certain kinds of studied individuals. First Bellanti Rep. at 3; R. Gherardi et al., *Macrophagic Myofasciitis Lesions Assess Long-Term Persistence of Vaccine-Derived Aluminium Hydroxide in Muscle,* 124 Brain 1821 (2001), filed as Ex. 26 (ECF No. 35-4) ("Gherardi"). Gherardi used electron microscopy to look for the presence of this aluminum adjuvant in the macrophages of 40 individuals who had been diagnosed with macrophagic myofasciitis ("MMF")—a wholly-distinguishable condition from AD, involving muscle tissue

[6] Macrophages are "any of the many forms of mononuclear phagocytes found in tissues." *Macrophage*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=29296&searchterm=macrophage (last visited Feb. 7, 2022). They have many functions including "nonspecific phagocytosis and pinocytosis, specific phagocytosis of opsonized microorganisms (mediated by Fc receptors and complement receptors); killing of ingested microorganisms; digestion and presentation of antigens to T and B lymphocytes; and secretion of many different productions, including enzymes (lysozyme, collagenases, elastase), acid hydrolases, several complement components and coagulation factors, prostaglandins and leukotrienes, and regulatory molecules such as interferon and interleukin-1." *Id.*

inflammation (rather than skin).[7] Gherardi at 1822. The adjuvant was detected in the lesions associated with MMF and deemed to have persistence there was well (when measured from the time of vaccination). *Id.* at 1829. In addition, certain animal studies specific to MMF (not the same condition as AD, it should be noted) revealed that "biopersistent nanomaterials" in MMF-impacted tissue (specifically the alum-based adjuvant) would later be taken up through an immune system-mediated process to the lymph nodes, eventually to circulate in the brain. First Bellanti Rep. at 3.

An infant like C.N., Dr. Bellanti concluded, was likely to experience "persistent systemic abnormalities in the skin and other organs" after vaccination. First Bellanti Rep. at 3. This, coupled with some underlying sensitivity to vaccination (as reflected in the fact that his siblings had also experienced eczema or other allergic conditions)[8] and/or genetic predisposition to AD generally, explained how vaccination might have caused C.N.'s symptoms. *Id.*

Second Report

Dr. Bellanti's next report was longer than the first, and was mostly a reaction to the opinion set forth by Respondent's expert (Dr. Gary Rachelefsky), contesting the accuracy of certain rebuttal points contained therein. Second Bellanti Rep. at 1.

First, Dr. Bellanti discussed Dr. Rachelefsky's contentions about susceptibility and what he termed "human immune system variation." Second Bellanti Rep. at 2. Vaccine reactions were not merely random, unpredictable transient occurrences (as Dr. Rachelefsky proposed), but instead reflected "human immune system variation"—a concept supported by literature. *Id.* at 2; P. Brodin & M. Davis, *Human Immune System Variation*, 17 NAT. REV. IMMUNOLOGY 21 (2017), filed as Ex. 29 (ECF No. 44-2) ("Brodin"). Brodin, Dr. Bellanti explained, observed the existence of specific "immunotypes," or subgroups of individuals whose reaction to different vaccines would be uncharacteristic of most individuals (and could in fact experience aberrant responses more often). Second Bellanti Rep. at 2.

Second, Dr. Bellanti attempted to bulwark his assertion that vaccination could effectively "prime" an aberrant immune response against unrelated antigens. Second Bellanti Rep. at 3. Viruses like the cytomegalovirus ("CMV"), he observed, had been found to have the capability to induce change in a host's immune response, even on reactivation, and could specifically increase

[7] In another case, I considered MMF, a "condition manifested by diffuse pain in the muscle(s) and highly specific myopathological [] alterations." *Morris v. Sec'y of Health & Hum. Servs.*, No. 12-415V, 2016 WL 3022141, at *3 n.9 (Fed. Cl. Spec. Mstr. Apr. 1, 2016). But I denied compensation, finding (among several things) that (a) the petitioner did not likely suffer from MMF, and (b) that the vaccines in question were not otherwise demonstrated to be capable of causing mylagias due to the adjuvants they contained. *Id.* at *11–13.

[8] As to the siblings, one had allergic rhinitis, which is closely tied to AD. Ex. 34 at 8 (ECF No. 56-2). Another sister also suffered from allergic rhinitis that was acute. *Id.* at 20, 22. C.N.'s final sibling also suffered from dermatitis and mild eczema. *Id.* at 26, 35.

the number of CMV-specific T cells. *Id.*; D. Furman et al., *Cytomegalovirus Infection Enhances the Immune Response to Influenza*, 7 SCIENCE TRANSLATES MEDICINE 281 (2015), filed as Ex. 30 (ECF No. 44-3) ("Furman"). The response to CMV could even impact the immune response to *different* viruses, like influenza. Second Bellanti Rep. at 3.

Finally, Dr. Bellanti took issue with what he deemed Dr. Rachelefsky's failure to acknowledge literature supporting the connection between several vaccines and AD. Second Bellanti Rep. at 3–4. One article, for example, had observed an increase of AD in approximately eight percent of children receiving the HiB vaccine (which was among the vaccines administered to C.N. on May 29, 2013). I. Wang et al., *Haemophilus Influenzae Type B Combination Vaccines and Atopic Disorders: A Prospective Cohort Study*, 111 J. of Formosan Medical Association 711, 716 (2012), filed as Ex. 32 (ECF No. 44-5) ("Wang"). Wang specifically used a prospective longitudinal cohort from Taiwan with a random sampling of 24,200 pairs of parents and newborns, after follow-up 20,172 children were part of the study. Wang at 712–13. A statistical analysis was then conducted dependent upon vaccination status. *Id.* at 713. But Wang's authors deemed the vaccine to have a "trivial adverse impact" risk, and noted the need for further investigation. *Id.* at 716–17.

Dr. Bellanti otherwise repeated his prior contentions that causation was established. Second Bellanti Rep. at 4. And he deemed the onset of C.N.'s AD to have occurred "in an appropriate timing" after receipt of the vaccines, although he did not expressly set forth (in this or his prior report) any details of *how long* a timeframe was medically acceptable, or why. *Id.*

Third Report

Dr. Bellanti's third report continued the back-and-forth with Dr. Rachelefsky. In particular, Dr. Bellanti critiqued Dr. Rachelefsky's rejection of the possible general association between vaccines and allergy/asthma, noting that the point was raised rhetorically by Dr. Rachelefsky but never addressed directly. Third Bellanti Rep. at 1. In so doing, Dr. Bellanti maintained that Dr. Rachelefsky had engaged in a "pedantic and somewhat rambling" discussion that was outdated in parts and ultimately did not support the conclusion that vaccines could not cause or exacerbate an allergic disease.

Dr. Bellanti then submitted in full an abstract that he reported had been presented at the Annual Meeting of the American College of Allergy, Asthma Immunology. Third Bellanti Rep. at 1–2; H. Mehta et al., *Allergic Reactions to Vaccines*, Ann. Allergy Asthma Immunology P148 (2012), filed as Ex. 38 (ECF No. 76-2) ("Mehta"). Mehta was a case report on two patients, one being an 11-year-old male and the second a 6-year-old male. Mehta at P148. The first had "developed respiratory distress, seizure-like stiffening, and a fever after administration of DTaP, Hib and Polio at his 2 month visit." *Id.* The second patient, after receiving boosters of DTaP and

pneumococcal vaccine "developed nodules at the injection site 1–2 days following administration, which thus far have persisted for 6 years." *Id.* This patient had "hypersensitivity to aluminum, neomycin and formaldehyde by patch testing which were present in these vaccines." *Id.* Its authors noted that reactions could be both local or systemic and immediate or delayed. *Id.*

Fourth Report

Dr. Bellanti's fourth report noted that he had reviewed C.N.'s siblings' medical records as well, determining that they also likely possessed a susceptibility for AD, albeit of a milder sort. Fourth Bellanti Rep. at 1. This difference did not, however, weigh against causation, since AD (the product of an interplay of environmental, genetic, and immunological factors) could result in different presentations in different individuals. *Id.* at 1–2.

Next, Dr. Bellanti offered two recently published articles or textbook selections (one of which he was the author) that he felt further underscored his theory's validity. Fourth Bellanti Rep. at 3; J. Bellanti, *Genetics/epigenetics/allergy: The Gun is Loaded…but What Pulls the Trigger?*, 40 Allergy Asthma Proc. 76 (2019), filed as Ex. 36 (ECF No. 62-2) ("Bellanti"); J. Kim et al., *Pathophysiology of Atopic Dermatitis: Clinical Implications*, 40 Allergy Asthma Proc. 84 (2019), filed as Ex. 37 (ECF No. 62-3) ("Kim"). Dr. Bellanti's own article discussed "the relationship of epigenetics[9] with genetics," showing how the latter was responsible for the former in determining expression of the genes. Fourth Bellanti Rep. at 3. Further, the article discussed how in general allergic diseases reflect chronic inflammation mediated by immunoglobulin E (IgE). Bellanti at 76. The article goes into detail on epigenetics and how the genotype is expressed into the phenotype of an allergic disease. *Id.* at 77, 81. The article reiterated the interplay between genetics, immunological development and environmental factors in the development of AD that Dr. Bellanti's prior reports had proposed. *Id.* at 82.

The second article, Kim, looked at "the role of genetic predisposition, epidermal barrier disruption, and dysregulation of the immune system are described together with epigenetics as critical components of AD." Fourth Bellanti Rep. at 3. This article addressed the filaggrin ("FLG") gene that encodes the FLG protein, and that, when mutated, could be associated with severe AD. Kim at 84. It also addressed the role of epigenetics in the regulation of gene expression without affecting the DNA sequence, specifically that environmental exposure induces such changes. *Id.* at 85. Kim also discussed the importance of damage to the skin barrier as encouraging heightened sensitization that could lead to the development of AD. *Id.* at 86. The rest of Kim focused mostly on the treatment of AD and different studies that have looked at treatment options. *Id.* at 87–89.

[9] Epigenetics is "the study of heritable changes in the function of genes that occur without changes in the DNA sequence, occurring during development and cell proliferation and including mechanisms such as DNA methylation, histone modification, and RNA interference." *Epigenetics*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=16848 (last visited Jan. 21, 2022).

B. *Dr. Gary Rachelefsky*

Dr. Rachelefsky filed three expert reports on behalf of Respondent. Report, dated July 18, 2017, filed as Ex. A (ECF No. 38-1) ("First Rachelefsky Rep."); Report, dated February 9, 2018, filed as Ex. B (ECF No. 47-1) ("Second Rachelefsky Rep."); Report, dated August 2018, filed as Ex. C (ECF No. 53-1) ("Third Rachelefsky Rep."). Dr. Rachelefsky proposed that C.N.'s AD predated vaccination, and could not otherwise be attributed to the vaccines he received regardless of C.N.'s genetic susceptibility to the skin condition.

Dr. Rachelefsky is a board-certified pediatrician with sub-specialties in allergy and immunology. Ex. A, Tab 29, dated November 21, 2016, at 1 (ECF No. 40-10) ("Rachelefsky CV"). He currently is a professor of allergy and immunology at the David Geffen School of Medicine at UCLA. *Id.* He also serves as the associate director of allergy-immunology training program at the UCLA School of Medicine. *Id.* He received his B.A. in Chemistry from Columbia University in New York, New York, and then attended Washington University in St. Louis, Missouri, for his medical degree. *Id.* He did a residency for pediatrics at the John Hopkins Hospital and two fellowships one at the Center for Disease Control in Atlanta, Georgia for epidemiology and the second at the UCLA School of Medicine in Los Angeles, California for allergy and immunology. *Id.* He currently holds memberships in several associations related to allergy, asthma, immunology, and pediatrics. *Id.* at 4. Dr. Rachelefsky has several other board member roles, trusteeships, and director positions. *Id.* at 6–9. He has published articles on immunity, epidemiology, pediatrics, rheumatic disease, and dermatitis. *Id.* at 12–24. He also has written chapters in books on allergies, pediatrics, and antihistamine and drug safety. *Id.* at 27–28.

First Report

Dr. Rachelefsky began his comment on the case by reviewing the clinical characteristics of AD. First Rachelefsky Rep. at 9. He defined AD as "a chronic pruritic inflammatory skin disease that occurs most frequently in children, but also affects adults." *Id*; J. Spergel, *From Atopic Dermatitis to Asthma: The Atopic March*, 105 ANN. ALLERGY ASTHMA IMMUNOLOGY 99 (2010), filed as Ex. A, Tab 2 (ECF No. 38-3); L. Eichenfield et al., *Atopic Dermatitis and Asthma: Parallels in the Evolution of Treatment*, 111 PEDIATRICS 608 (2003), filed as Ex. A, Tab 3 (ECF No. 38-4). AD often has a familial association, with roughly "70 percent of patients hav[ing] a positive family history of atopic diseases." First Rachelefsky Rep. at 9.

Next, Dr. Rachelefsky discussed the pathogenesis of eczema. First Rachelefsky Rep. at 12. Although it has long been considered primarily an immunological disease, more recently epithelial barrier dysfunction has been found to be a likely factor in its development. *Id.* Thus, AD's pathophysiology most likely reflects the interaction between "[a] leaky skin epithelial barrier combined with abnormal immune responsiveness." *Id.* He added that "a genetically impaired skin

barrier function…*may be present at birth and predict the development of atopic dermatitis in the first year of life*." *Id.* at 13 (emphasis added); M. Moore et al., *Perinatal Predictors of Atopic Dermatitis Occurring in the First Six Months of Life*, 113 PEDIATRICS 468 (2004), filed as Ex. A, Tab 14 (ECF No. 39-5) ("Moore").

Dr. Rachelefsky then opined as to whether vaccination could *also* play a role in AD's development. Vaccines, he explained, are used to enhance antibody responses in individuals, in many instances through the inclusion of adjuvants. First Rachelefsky Rep. at 14. Aluminum salt adjuvants are approved in vaccines for this very purpose, and are well understood to be safe. *Id.* at 14, 15; N. Garçon et al., *Evolution of Adjuvants Across the Centuries, in* VACCINES 58 (Plotkin S. Orenstein et al. eds., 6th ed. 2013), filed as Ex. A, Tab 25 (ECF No. 40-6). Dr. Rachelefsky was otherwise unable to find any literature connecting vaccines and AD, or anything suggesting that they could prime the body to be more sensitive in reaction to external stimuli. First Rachelefsky Rep. at 17. And none of the vaccines C.N. received were live vaccines that would require an actual response to viral replication (and thus the risk of a heightened immune reaction). *Id.* He thus expressed the view that "routine vaccination would have no role in the pathogenesis of atopic dermatitis." *Id.* at 13.

In addition, Dr. Rachelefsky opined that the medical literature evidence offered by Dr. Bellanti to show how vaccination might propagate AD was ultimately insufficient. Kasraie & Werfel, for example, merely observed that macrophage immune cells were one of several pathogenic factors driving AD—not that their existence or behavior was impelled by vaccination. First Rachelefsky Rep. at 17. The second, Gatti & Montonardi, just provided a hypothesis with no evidentiary support, and otherwise did not reliably show vaccines could be causal of AD. *Id.* at 19. And Gherardi focused on MMF—an extremely rare disease that is found in middle-aged adults, and thus has nothing to do with this case. *Id.*

Dr. Rachelefsky concluded with observations about the actual medical record and how it was inconsistent with Petitioner's causation theory. He emphasized that Dr. Bellanti had neglected to note that, as the record established, C.N.'s AD began *prior* to his immunizations. First Rachelefsky Rep. at 16. In addition, C.N. had other warning signs in his medical history: "infantile eczema [], including positive family history, onset by 0-3 months of age, its persistence through childhood, the significant atopic component, food desensitization, the 'march' to asthma and allergic rhinitis, etc." *Id.* at 17. The fact that C.N.'s siblings had experienced AD as well only underscored the genetic basis for the condition as more likely than vaccination. *Id.* at 18.

Second Report

Dr. Rachelefsky's second report proposed two ways vaccines could be causal of AD—either by enhancing the "immune response to allergen via TH2 cells [a kind of T cell that assists

the production of antibodies]," or by "preventing childhood infection (that would normally cause a shift from newborn TH2 immune response to a TH1 response)" that would have the adverse impact of more allergies, a theory he characterized as the "hygiene hypothesis." Second Rachelefsky Rep. at 2. He dismissed out of hand the second, reasoning that children were exposed to far more different wild viruses than the more limited number of vaccines specific to only a handful of viruses, making it unlikely that "the immune system would rely on only a few infections" to balance the T-cell helper response. *Id.*

But the first theory (in which vaccination more directly impacted the T helper cell response to allergens) was also in his view flawed. Existing vaccine surveillance data reviewed little in the way of "environmental allergen priming" attributable to vaccines, even though they were often manufactured from components that could trigger an allergic response (like egg proteins). Second Rachelefsky Rep. at 2. Moreover, it appeared that vaccines might actually be capable of *preventing* allergy. *Id.* at 3; C. Grüber et al., *Do Early Childhood Immunizations Influence the Development of Atopy and Do They Cause Allergic Reactions?*, 12 PEDIATR. ALLERGY IMMUNOL. 296 (2001), filed as Ex. B, Tab 4 (ECF No. 47-5) ("Grüber"). And vaccine adjuvants had not been demonstrated to cause allergic responses at the situs of inoculation. Second Rachelefsky Rep. at 3; H. Kobayashi et al., *Immunostimulatory DNA Prepriming: A Novel Approach for Prolonged Th1-Biased Immunity*, 198 CELL IMMUNOL. 69 (1999), filed as Ex. B, Tab 7 (ECF No. 47-8).

Relatedly, Dr. Rachelefsky observed, there were two theories for AD pathogenesis generally (independent of the role a vaccine might play): "inside out" (dysregulation of the immune response at the locus of the skin, causing rash) versus "outside in" (defects in the skin barrier attributable to some internal body pathologic process). Second Rachelefsky Rep. at 1. Dr. Bellanti's causation theory relied on an "inside out" mechanism (with the vaccine triggering an aberrant immune reaction leading to AD's clinical symptoms), but Dr. Rachelefsky could not find literature support for it. *Id.* at 3–4. More recently-filed items of literature like Brodin, he maintained, largely focused on immune variation in the human population or different autoimmune diseases like lupus—not AD. *Id.* at 4–5. Furman similarly addressed only the impact a CMV infection would have on antibody responses to a subsequent flu vaccine, and did not otherwise address vaccine causality in the context of AD. *Id.* at 5. And Wang's own authors emphasized the weakness of their findings in associating the HiB vaccine (in limited circumstances) with AD. *Id.* at 6; Wang at 713, 717.

In fact, Dr. Rachelefsy reasoned, given the prevalence of AD in children in the U.S., its incidence should be far *more* common if vaccination were so capable of triggering it, given the number of vaccines infants received. Second Rachelefsky Rep. at 7. The fact that AD was not undermined the conclusion that vaccines could be causal—and Dr. Rachelefsy offered many items of literature to support this point. *Id.* at 8–13; I. Kummeling et al., *Diptheria Pertussis, Poliomyelitis, Tetanus, and Haemophilus Influenzae Type b Vaccinations and Risk of Eczema and Recurrent Wheeze in the First Year of Life: The KOALA Birth Cohort Study*, 119 PEDIATR. e367

(2007), filed as Ex. B, Tab 14 (ECF No. 48-5) ("Kummeling"). Kummeling's authors evaluated 2,764 families with infants six months old, comparing the unvaccinated or incompletely-vaccinated (for the three kinds of vaccines considered) with those who had been vaccinated for incidence of eczema or recurrent wheeze, finding that no difference. Kummeling at e368. By contrast, other studies did show risk increases from different environmental factors, like fungi in the home. Second Rachelefsky Rep at 8; I. Wang et al., *Environmental Risk Factors for Early Infantile Atopic Dermatitis*, 18 PEDIATR. ALLERGY IMMUNOL. 441 (2007), filed as Ex. B, Tab 15 (ECF No. 48-6). Some studies similarly found genetic risks and different environmental contributing factors to be significant to AD's development—but not vaccines. D. Purvis et al., *Risk Factors for Atopic Dermatitis in New Zealand Children at 3.5 Years of Age*, 152 BRITISH J. DERMATOLOGY 742 (2005), filed as Ex. B, Tab 16 (ECF No. 48-7) ("Purvis"); Moore. He also referenced literature suggesting that AD was more prevalent in Asian children, like C.N., and more severe as well. Moore at 472.

Third Report

Dr. Rachelefsky's third report attempted to refute or address certain rebuttal points leveled against his second report by Dr. Bellanti.

In particular, Dr. Rachelefsky denied that he had failed to "answer" his question of whether vaccines can cause allergies and asthma, noting that the numerous items of literature he had referenced had consistently failed to identify vaccines as causal. Third Rachelefsky Rep. at 2. While the underlying ingredients of vaccines, like egg proteins, might be the source of allergic reactions in some instances, there was in his view no support for the conclusion that the vaccine's *primary* antigenic components could trigger atopic disease. *Id.* The same was true of vaccine preservatives or adjuvants, all of which might occasionally cause a delayed-type hypersensitivity reaction but not disease itself. *Id.* at 3. At most, a variety of "[n]on-allergic systemic reactions" were possible (malaise, transient skin rash, muscle pain, etc.), but this was not congruent with "systemic IgE [antibody] mediated reactions" resulting in a chronic form of eczema/AD. *Id.* And Dr. Rachelefsky reiterated his earlier assertion that literature refuted the contention that vaccines were correlated with asthma.

In the context of the above, Dr. Rachelefsky also repeated his argument that T helper cell balances were not likely impacted by vaccination (whether due to a vaccine's adjuvants or otherwise). Third Rachelefsky Rep. at 4. He allowed that this class of T cells (which itself is diverse) was part of the "complex immune network that contributes to the cutaneous inflammation in [AD]. *Id.* In particular, such immune cells promoted the cytokines associated with the inflammation characteristic of, and required for, AD. *Id.* Nevertheless, he again emphasized that larger studies identified no relationship between atopy and vaccines. *Id.* at 5; J. Kelso et al., *Adverse Reactions to Vaccines Practice Parameter*, 103 J. ALLERGY CLIN. IMMUNOLOGY S1

(2009), filed as Ex. C, Tab 15 (ECF No. 54-6) ("Kelso").[10] At most, vaccines could produce rare allergic responses due to their ingredients, or transient localized reactions (although they would have non-allergic mechanism). Third Rachelefsy Rep. at 6.

Finally, Dr. Rachelefsky addressed Mehta, the abstract Dr. Bellanti included in his third report that considered two cases of post-vaccination allergic responses. Dr. Rachelefsky disputed its relevance, noting that (a) it involved older children rather than infants like C.N., (b) did not involve AD specifically, and (c) was a mere abstract was not scientifically reliable for purposes of evaluating causation. Third Rachelefsky Rep. at 7.

II. Procedural History

The claim was initiated in February 2016, with medical records filed on several occasions thereafter. Respondent filed his Rule 4(c) Report on June 30, 2016. ECF No. 19. The parties then exchanged expert reports, with four from Petitioner and three from Respondent, as detailed above. The case was reassigned to me on March 2, 2021. Order, dated March 2, 2021 (ECF No. 68). I thereafter proposed that the matter be resolved via ruling on the record, and both sides filed briefs in support of their positions. Petitioner's Motion, dated May 5, 2021 (ECF No. 71) ("Mot."); Respondent's Opposition, dated July 13, 2021 (ECF No. 73) ("Opp."); Reply, dated Aug. 8, 2021 (ECF No. 75) ("Reply"). This case is now ripe for resolution.

III. Parties' Arguments

A. *Petitioner*

Petitioner maintains that C.N. had a pre-vaccination susceptibility to AD[11] that was likely aggravated by the vaccines he received. Mot. at 12. As to *Althen* prong one, Petitioner argues that "microbial antigens, adjuvants, or other excipient materials found in vaccines," cause immune dysregulation and inflammation leading to "systemic abnormalities in the skin and other organs." *Id.* at 12–13; First Bellanti Rep. at 3. Medical literature has also shown that immune cytokines can influence the skin barrier and allergic inflammation. Mot. at 13; Kim at 85. Thus, although genetics play a large role in determining the risk factor for a specific individual, C.N.'s individual genetic susceptibility only manifested *after* his exposure to the vaccines. Mot. at 13–15; Brodin at 10.

Although Petitioner to some extent defended the lack of direct evidence associating vaccination with AD on the grounds that the injury was rare (and therefore somewhat undetectable by epidemiologic studies), she did highlight a number of filed articles supporting her claim. For

[10] Kelso actually lists Dr. Bellanti as a co-editor. Third Rachelefsky Rep. at 5; Kelso at S1.

[11] Petitioner does not formally maintain a significant aggravation claim, however, and does not concede C.N.'s AD had already begun pre-vaccination but was worsened by it.

example, she pointed to Wang as supporting the conclusion that aluminum salts "can induce an elevated humoral response that is associated with a predominant TH2-type immune response." Mot at 16; Wang at 4. She also stressed the fact that some articles filed in this case by Respondent in fact showed an increased risk of post-vaccination AD (or comparable allergic conditions), involving vaccines comparable to what C.N. had received. Mot. at 18-19; S. Bremner et al., *Timing of Routine Immunisations and Subsequent Hay Fever Risk,* 90 ARCH. DIS. CHILD 567, 570 (2005), filed as Ex. B, Tab 20 (ECF No. 49-1) ("Bremner") (finding a protective impact from delay of infant receipt of DPT or MMR vaccines, although adding that those vaccinated in accordance with usual schedules were not at any greater risk than unvaccinated infants); E. Farooqi & J. Hopkin, *Early Childhood Infection and Atopic Disorder,* 53 THORAX 927 (1998), filed as Ex. B, Tab 13 (ECF No. 48-4) ("Farooqi") (stating the receipt of whole-cell pertussis vaccine (not equivalent to the acellular version at issue) associated with development of atopic disease).

In addition (and although not a specific requirement to prove causation), Petitioner argued that Dr. Bellanti had established a likely biological mechanism for causing C.N.'s injury. Mot. at 17. Specifically, in AD macrophages cause or promote inflammatory activity that persists, resulting in chronic inflammation. Kasraie & Werfel at 1. Relying on literature specific to MMF, Dr. Bellanti had demonstrated how the persistence of these adjuvants can stimulate these macrophages. Mot at 17. Overall, medical literature filed in this case supported the determination that C.N.'s AD is an "allergic disease" triggered by receipt of multiple vaccines at once. *Id.* at 19–20.

Petitioner further maintained that the record supported the conclusion that C.N.'s vaccinations caused his AD. Mot. at 22 (citing Fourth Bellanti Rep. at 3). She noted that C.N.'s two siblings also displayed a history of eczema, establishing his own genetic susceptibility even if their manifestations were much milder. Mot. at 21–22. Prior to his vaccinations, C.N. was healthy—and any AD-like symptoms he may have displayed were nothing more than "routine, childhood eczema"—distinguishable from his later symptoms. *Id.* at 23. Thereafter, however, he had a fever and would not sleep. *Id.* at 24. The reaction worsened more after the four-month vaccines in June 2013, and his symptoms were resistant to treatment. *Id.* at 25. Finally, Petitioner noted that the one-week onset of AD after C.N.'s May vaccinations was consistent with the timeframe proposed in Dr. Bellanti's report. Mot. at 28. Thus, the third causation test prong was met.

Petitioner's reply almost solely addressed a single new article submitted by Respondent with their opposition brief. M. Ayasse et al, *Vaccines Do Not Cause Atopic Dermatitis: A Systematic Review and Meta-Analysis*, 39 Vaccine 1805 (2021), filed as Ex. D (ECF No. 74) ("Ayasse").[12] Ayasse is a meta-analysis of 37 previous articles published from 1997 to 2018,

[12] Although Ayasse was filed late in the proceedings, it was only accepted for publication in February 2021—and hence a few months before briefing the ruling on the record. Ayasse at 1. It is therefore in fact a relatively new

including some of those cited by the experts in this case. *Id.* at 2, 4–5 (including Kummeling in meta-analysis). Its authors found "no consistent associations of vaccination" with AD regardless of vaccine regimen. *Id.* at 6. Moreover, the prevalence of AD amongst the unvaccinated exceeded that of recipients of any particular vaccine (although amongst vaccines specifically, AD was most associated with pertussis-containing vaccines). *Id.* at 3–5. AD was also more prevalent among the population of studied patients who received single vaccines than multiples (as was the case here), although in this sub-analysis the odds of AD were comparable amongst the vaccinated and unvaccinated. *Id.* at 5.

Ayasse, Petitioner maintained, is "seriously misleading," and ultimately not reliable. Reply at 1–2. The fact that Ayasse was nothing more than a summary of individual studies meant that error or bias in any single considered study infected the whole, Petitioner argued. Indeed, Petitioner observed "carelessness in abstracting and summarizing appropriate studies, failure to consider important covariates, bias on the part of the meta-analyst and overstatements of the strength and precision of the results of the studies included in the analysis all have contributed to an invalid meta-analysis" (*Id.* at 2)—although the Reply does not specifically identify any examples. At most, Petitioner argued, Ayasse corroborated the rareness of vaccine injury (and the concordant difficulty Program petitioners invariably have in locating literature to support their claim). Reply at 2.

B. *Respondent*

Respondent argues that Petitioner has not established that Dr. Bellanti's medical theory of "immune dysregulation and inflammation specifically applies to C.N.'s case." Opp. at 10. Although much of Dr. Bellanti's theory discusses how immune reactions are person-specific, or how individuals may be genetically predisposed to conditions like AD, all this establishes simply that these factors, rather than the vaccine, better explain the injury's etiology. *Id.* at 11. Otherwise, as Dr. Rachelefsky established, Petitioner did not offer sufficient proof linking vaccines to AD's pathogenesis, while Respondent cited in his reports literature (including epidemiologic evidence) that refuted the alleged association. *Id* at 11–12.

As to *Althen* prong two, Respondent argued that C.N.'s genetic susceptibility to AD was a better causal explanation for the injury. Opp. at 13. In addition, no treaters opined the vaccinations were causal, and no record evidence showed elevated post-vaccination levels of vaccine adjuvants or other contaminants that could (under Dr. Bellanti's theory) purportedly encourage macrophage activity. *Id.* at 14–15. The medical record also revealed that C.N. was experiencing eczema *the same day* he received his two-month vaccinations in May 2013. *Id.*

publication—and Petitioner did have the opportunity to consider its contents (reflected in the fact that her Reply focused closely upon it).

C.N.'s pre-vaccination AD also undercut Petitioner's prong three showing. Opp. at 16. Dr. Bellanti's contention that the literature supported a short timeframe for vaccine-induced onset only tended to demonstrate that AD's onset often occurred concurrently, and hence coincidentally, at the same time children were receiving early-infant vaccinations. *Id.* at 16–17; Second Bellanti Rep. at 4; Third Bellanti Rep. at 3. Thus, the fact that "[t]emporally-speaking, many AD sufferers develop symptoms around the time they receive childhood vaccinations . . . does not imply that vaccines cause atopic disorders." Opp. at 17.

Finally, Respondent addressed the prongs required to establish significant aggravation (even though Petitioner does not style her claim as such). Opp. at 17. And Respondent filed, and discussed, Ayasse, noting that it found "no consistent associations of vaccination by any regimen" with AD. *Id.* at 6.

IV. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove that: (1) they suffered an injury falling within the Vaccine Injury Table (i.e., a "Table Injury"); or (2) they suffered an injury actually caused by a vaccine (i.e., a "Non-Table Injury.) *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano*, 440 F.3d at 1320. In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter., Inc. v. United States*, 6 Cl. Ct. 476, 486 (1984) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). On one hand, proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). But on the other hand, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a

Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Each *Althen* prong requires a different showing and is discussed in turn along with the parties' arguments and my findings.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

However, the Federal Circuit has *repeatedly* stated that the first prong requires a preponderant evidentiary showing. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) ("[w]e have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard"); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010). This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted). If a claimant must *overall* meet the preponderance standard, it is logical that they be required also to meet each individual prong with the same degree of evidentiary showing (even if the *type* of evidence offered for each is different).

Petitioners may offer a variety of individual items of evidence in support of the first *Althen* prong, and are not obligated to resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). No one "type" of evidence is required. Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu,* 569 F.3d at 1380. Nevertheless, even though "scientific certainty" is not required to prevail, the individual items of proof offered for the "can cause" prong must *each* reflect or arise from "reputable" or "sound and reliable" medical science. *Boatmon,* 941 F.3d at 1359-60.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually

supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (stating it is not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Hum. Servs.*, No. 06–522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356–57 (2011), *aff'd without opinion*, 475 F. App'x. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11–355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people are likely to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral

testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are automatically deemed accurate, or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Evaluation of Expert Opinions*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed.

Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Disposition of Case Without Hearing*

I am resolving this case on the papers, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Atopic Dermatitis as Vaccine Injury

The parties largely agreed on what AD is, and there is no dispute that C.N. has been properly diagnosed with it. AD is thought to begin in children before they are five, and may persist into adolescence and adulthood. *Atopic Dermatitis (Eczema)*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/atopic-dermatitis-eczema/symptoms-causes/syc-20353273 (last visited Jan. 20, 2022). Symptoms can flare and wane over several years. *Id.* The primary risk factor for its development is thought to be a personal or family history related to "eczema, allergies, hay fever or asthma." *Id.* An affected child's skin may then be further impacted by environment or irritants. *Id.*

Very few Program cases have addressed AD as a vaccine injury—and none have resulted in entitlement determinations for the claimant. *See,* e.g., *Perekotiy v. Sec'y of Health & Hum. Servs.*, No. 16-997V, 2020 WL 12904810, at *1 (Fed. Cl. Spec. Mstr. Apr. 20, 2020), *mot. for review den'd* 2020 WL 5887548 (Fed. Cl. Sep. 17, 2020) (unreported decision). In *Perekotiy* (a case I decided), a claimant argued that her child had developed a dermatological reaction after receiving the Hepatitis B vaccine, and then that the DTaP and IPV vaccines worsened it. *Perekotiy,* 2020 WL 12904810, at *14. That petitioner specifically reasoned that the vaccines produced a "delayed IgE-mediated response, leading to an increased production of inflammatory eosinophils." *Id.* In denying compensation, I found that insufficient evidence supported the theory, while reliable literature (some of which was also filed in this case)[13] undercut the proposed association. *Id.* at *27. In addition, I found significant aggravation by vaccination was unlikely, since a patient with AD will display future additional sensitivity to *any* stimuli, vaccine or not, rendering them more disposed to experience other IgE-mediated inflammatory reactions regardless of what first instigated the condition. *Id.* at *29.

The result was the same in an earlier case involving the allegation that the DTaP vaccination caused the claimant's minor child's food allergies and skin disease. *Wood v. Sec'y of Health & Hum. Servs.*, No. 15-1568V, 2018 WL 1150730, at *1 (Fed. Cl. Spec. Mstr. Feb. 1, 2018). The child therein had experienced a dry rash a week after vaccination, but later tested positive for a number of food allergies. *Wood*, 2018 WL 1150730, at *2 The claimant alleged that a beef residue contained in the vaccine worked in tandem with a milk allergy to result in a reaction. *Id.* at *3. But the special master deciding the case found the theory unpersuasive, noting as well the lack of increase in food sensitivities from epidemiological studies, undermining the idea that they could trigger an immune response of the kind the child experienced. *Id.*

II. Petitioner Has Not Carried Her Burden of Proof

A. *Althen Prong One*

The causation theory offered by Dr. Bellanti never rose above the level of mere plausibility, and thus was not preponderantly established with sufficient reliable evidence to meet the "can cause" *Althen* element. Admittedly, the theory was rooted in several persuasive and medically/scientifically reliable points. Thus, Dr. Bellanti established that immune system reactions likely vary from person to person due to inherent genetic differences; that AD itself has a strong genetic component, making some individuals more susceptible; and that an immune reaction plays a role in AD's clinical presentation as well as likely pathogenesis.

But far less reliable proof was offered to link vaccinations—whether specific ones

[13] *See e.g.* Grüber.

commonly administered to infants, like the DTaP, or a series of several administered simultaneously—to AD, even in a susceptible person. Dr. Bellanti unpersuasively invoked distinguishable diseases, like MMF, attempting to draw a parallel between them and AD simply because MMF is associated with adjuvants found in macrophages (the same immune cells he proposed were driving AD). He could not reference his own specific immunologic research into vaccines to connect them to AD, and instead cited articles like Wang, which (although it showed some degree of HiB vaccine/AD association) were by their own terms not especially probative as to causation. Or he referenced case reports like Mehta, which are well understood in the Program to provide small support for causation. *Crutchfield v. Sec'y of Health & Hum. Servs.*, No. 09-39V, 2014 WL 1665227, at *19 (Fed. Cl. Spec. Mstr. Apr. 7, 2014) ("single case reports of Disease X occurring after Factor Y . . . do not offer strong evidence that the *temporal* relationship is a *causal* one—the temporal relationship could be pure random chance") (emphasis in original), *aff'd*, 125 Fed. Cl. 251 (2014). In the end, Dr. Bellanti simply seemed to conclude that that temporal association between purported onset and C.N.'s vaccinations suggested a causal relationship—for reasons that relied on general knowledge about the immune response rather than sufficient specific evidence demonstrating how the response to vaccination (driven by an innate immune response involving cytokines or some reaction to other vaccine components) would "open the door" to AD.

Dr. Rachelfsky, by comparison, did a better job undermining Petitioner's causation conclusions. Both experts possessed sufficient general qualifications to comment on immunologic issues as well as allergic conditions comparable to AD. But overall Dr. Rachelefsky's reports more directly addressed the issue of whether vaccines could cause AD. And he did not merely deny knowledge of reliable science in the medical community to support the contention, but instead referenced specific items of literature that backed up his arguments. *See,* e.g., Grüber; Kummeling; Kelso. (By contrast, other than Wang, Petitioner mostly looked for evidence of a vaccine association in literature filed by Respondent, like Bremner and Farooqi—even though Dr. Rachelefsky filed far more items that were unsupportive of Petitioner's theory). While both experts engaged in a bit of "tit for tat" in attacking the other's contentions that reduced the overall value of their exchanges, my ultimate conclusion is that Dr. Rachelefsky's reports were more specific in their exploration of whether and how vaccines, singularly or administered together, could cause AD—and his reliance on more direct science pertaining to that topic (rather than Dr. Bellanti's broader discussion of immune variance in the human population) made his overall opinions more persuasive.

There is also the matter of Ayasse—a review article referencing numerous smaller-scale epidemiologic studies and other scientific assays, and strongly undermining Petitioner's theory as a result. In reaction, Petitioner has not raised specific reasons for doubting Ayasse's conclusions—for example, by identifying, among the 37 studies it relies on, examples of bias or scientifically-unreliable methodologies. Instead, she has attempted to minimize Ayasse categorically, deeming it contrary to the evidentiary standards of the Program. Since vaccine injuries are rare, Petitioner

reasons, and since they can never be completely ruled out by even the most statistically-reliable epidemiologic evidence, then what use is this kind of evidence at all? Reply at 2–3. If I give it weight, am I not then *requiring* Petitioner to offer counter-epidemiologic evidence—something the Circuit prohibits?

The answer is no—although some elaboration on the evidentiary standards applicable to Program cases (and to the "can cause" prong specifically) helps to illustrate why. As is well understood, Vaccine Program claimants must only prove their claim *preponderantly*, not to a scientific/medical degree of certainty. *Moberly*, 592 F.3d at 1322. This means that claimants can carry their burden of proof, and receive compensation as a result, *despite* an abundance of *uncertainty* that the relevant vaccine could, or in fact did, cause the injury. A showing that is 52 percent preponderant carries the day but still leaves 48 percent of doubt.[14] Although (unlike with a Table claim, where causation is presumed) establishing the "can cause" prong is never a given (and claimants often fail to do so), the standard's general leniency reflects the remedial and generous nature of the Program, and implicitly takes into account the fact that it is inherently difficult for claimants to prove causation "in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280.

The benefit the preponderant standard provides to petitioners is also reflected in a second, related accommodation: petitioners may satisfy their evidentiary standard with a wide array of evidence, *all* of which the special master must consider. No one category of evidence is required (beyond core issues like proof of vaccination or medical record proof of an injury). Thus, in some cases a petitioner could prevail without offering a single item of literature, or an expert opinion.

However, in all cases a preponderant showing *must* be made, no matter the combination of evidence used to do it. The absence of some kinds of evidence (for example, an expert report in a case involving a complex causation theory or thorny diagnostic issue) can limit a petitioner's success in crossing the preponderant "line," depending upon the case or science involved. As a result, it is very common for claimants to offer types of evidence that they are otherwise not literally required to marshal. Petitioners' experts, for example, often propose a biologic mechanism for how a vaccine could provoke an aberrant immune response resulting in disease, since such a showing (if reliable and persuasive) may go a long way to establishing preponderance. This occurs despite ample Federal Circuit precedent establishing that proof of mechanism is not required. *Andreu*, 569 F.3d at 1378–79.

The Respondent is similarly not prohibited from offering any class of evidence in

[14] Of course, special masters never calculate the degree of preponderance established in terms of percentages. But I do note distinction in the degree of proof offered in deciding entitlement cases—some matters result in a near "tie" (in which case the goals of the Program support a decision for the claimant), some clearly do not cross the preponderant line, and some can satisfy preponderance even where Respondent has raised reasonable objections to the theory presented.

attempting to *rebut* a petitioner's theory of causation. It is for this reason Respondent will in some cases identify relevant, on-point epidemiologic evidence that undercuts the petitioner's showing. The Circuit has recognized the relevance of such evidence to Vaccine Act cases, and the reasonableness of special masters in evaluating it. *D'Tiole v. Sec'y of Health & Hum. Servs.,* 726 F. App'x 809, 811 (Fed. Cir. 2018) ("[n]othing in *Althen* or *Capizzano* requires the Special Master to ignore probative epidemiological evidence that undermines petitioner's theory").

Petitioners can make any number of persuasive and compelling points against an item of epidemiologic literature (that the study is not reliable, that its sample size is inadequate, that it would not have included in the sample individuals comparable to the petitioner, etc.), and I have credited such arguments in my weighing of a specific item of literature. *But petitioners cannot simply disclaim the relevance of such literature outright by arguing that considering it amounts to requiring* ***they*** *produce it as well.* This is wholly incorrect, and the mere assertion of such an argument reflects more the petitioner's desire to *lower* the burden (by stopping the special master from weighing *all* evidence offered pro and con) than a proper interpretation of the Vaccine Program's evidentiary standards.

In short: I am empowered to consider an article like Ayasse despite the fact that it cannot conclusively disprove causation, and I may give it evidentiary weight. Here, I conclude that although Ayasse does not fully rebut Petitioner's arguments—and certainly makes her theory no less *plausible*, especially since vaccine injuries are rare events—it *does* greatly undermine the conclusion that AD could be caused by an infant's receipt of several vaccines at once. And it is consistent with Dr. Rachelefsky's opinion, plus the literature he initially offered in support. Petitioner has not in this case carried her preponderant burden of proof on the first *Althen* prong.

B. *Althen Prong Two*

As noted, there is no dispute about C.N.'s diagnosis—but there is some disagreement as to whether he already had AD as of May 29, 2013, when he received the first series of vaccines relevant to this claim. I find the record more likely than not suggests that he did, since he presented with AD symptoms at that time (dry cheeks and scalp, eczema). Petitioner tries to distinguish these presenting symptoms by suggesting they reflect "routine" eczema inconsistent with what he later displayed, but the fact that initial symptoms were less severe does not prevent the conclusion that they were the onset of a progressive condition that may in fact have worsened somewhat later. Thus, the initial series of vaccines C.N. received on the same day (but slightly after) his symptoms were first noted could not have caused his AD. *Shalala v. Whitecotton*, 514 U.S. 268, 273–274 (1995) (a Vaccine Act claim must establish that the injury in question did not precede the relevant vaccine's administration).

Absent the above, resolution of the second prong would present a slightly more difficult

question, but I find on this record the evidence would still preponderate against Petitioner. I give some weight to Petitioner's contentions that C.N. experienced fever and malaise the day of his May 2013 vaccinations—although there is a subsequent lack of record corroboration for the conclusion that his reaction had a significant skin-related component. The next medical records filed in this case are from late June 2013, when C.N. received the next set of vaccines—and comments in those records about his skin condition do not display considerable concerns that can be meaningfully differentiated from what was expressed in May. Ex. 7 at 23. The subsequent records thereafter do not disclose an effort to treat him in reaction to the next round of vaccines. And no treaters have embraced the contention that any of these vaccines caused C.N.'s AD, despite its persistence.

C. *Althen Prong Three*

The literal timeframe in which C.N. is alleged to have experienced vaccine-induced onset of AD—within several days to a week of vaccination, as primarily evidenced by Petitioner's personal testimony of C.N.'s post-vaccination fever/malaise, and then her observations of rash—is certainly consistent with Dr. Bellanti's theory for how long it would take for a cytokine-driven innate immune response from the vaccines to manifest skin problems, via his "inside-out" theory. But there are two problems that ultimately result in this prong not being successfully established.

First, and of greatest significance, is my finding that C.N. likely already had AD as of the date of his May 29, 2013 vaccinations. Onset *predated* vaccination—meaning it could not have been vaccine-caused, regardless of the theory for when it might be thought to appear due to a vaccine. But there is also a second deficiency in Petitioner's showing on this prong, which stems from imprecision in Dr. Bellanti's opinion. Dr. Bellanti devotes little of his analysis to showing how onset was medically reasonable, relying instead on conclusory declarations that the timeframe has been preponderantly established, but with no discussion (bulwarked with other evidence) for why or how. *See,* e.g., Second Bellanti Rep. at 4; Third Bellanti Rep. at 3. Petitioner's briefing attempts to fill that hole, but she only offers studies, like Wang, that observe the time of life *when* infants develop AD (i.e., between 18 months and two years of age)[15]—*not* how long after vaccination it would clinically appear. There is simply not enough in this record to find that a medically acceptable timeframe for AD's vaccine-induced onset has been established.

III. Petitioner Did Not Establish Significant Aggravation of C.N.'s AD

Petitioner has not formally alleged that C.N.'s AD was significantly aggravated by the vaccines he received, based on the six-prong test set in *Loving v. Sec'y of Health & Hum. Servs*.,

[15] I also note that these ranges are longer than when C.N. (who was less than four months old during the timeframe of vaccination) is alleged to have developed AD, although Petitioner's intent in offering the 18 months to two-year timeframe may have been to set forth age limits rather than narrow windows in which AD might first manifest.

86 Fed. Cl. 135, 144 (2009).[16] Indeed, she maintains any presenting symptoms of AD at the time of vaccination in May 2013 were distinguishable. Mot. at 23. At most, she argues that C.N. was *predisposed* to experience AD, and that the vaccines he received unmasked it and/or "worsened" it only to the extent that he was asymptomatic before. *Id.* at 12, 24–25. This amounts to a regular claim under *Althen*—since in many non-Table causation cases, a number of factors (some genetic) may contribute to the injury, but there was *no* injury before, and the vaccine is the main reason for it.

A significant aggravation claim, by contrast, has as its foundation the admission by a claimant that he *did* have some pre-vaccination injury but that the injury worsened due to the vaccine. *Hennessey v. Sec'y of Health & Hum. Servs.*, No. 01-190V, 2009 WL 1709053, at *42 (Fed. Cl. Spec. Mstr. May 29, 2009) (critical point of examination is "whether the change for the worse in [petitioner's] clinical presentation was aggravation or a natural progression" of the underlying condition), *mot. for review denied*, 91 Fed. Cl 126 (2010). And Petitioner does highlight in her brief the fact that C.N. was largely healthy and without symptoms before the vaccination series began. Mot. at 1–2.

Regardless, Petitioner also seems to "hedge her bets," allowing for a possible finding that the skin rash symptoms C.N. presented with on May 29, 2013, could be construed as the onset of his AD—in which case, she conclusory states in her brief, "C.N.'s subsequent AD symptoms would certainly be characterized as a significant aggravation." Mot. at 23. As a result, Respondent has gone to the trouble of briefing the *Loving* elements. Opp. at 17–21.

I again emphasize that Petitioner has made no effort to substantiate a significant aggravation claim as an alternative basis for entitlement, and thus her brief is silent on how she

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[16] The *Loving* test's elements require establishing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

In *Sharpe v. Sec'y of Health & Hum. Servs.,* 964 F.3d 1072 (Fed. Cir. 2020), the Federal Circuit further elaborated on the *Loving* framework. Under Prong (3) of the *Loving* test, the Petitioner need not demonstrate an *expected* outcome, but merely that her current-post vaccination condition was worse than pre-vaccination. *Sharpe*, 964 F.3d at 1081. And a claimant may make out a prima facie case of significant aggravation overall without eliminating a preexisting condition as the potential cause of her significantly aggravated injury (although the Circuit's recasting of the significant aggravation standard still permits Respondent to attempt to establish alternative cause, where a petitioner's showing is enough to make out a prima facie case and thereby shift the burden of proof to Respondent). *Id.* at 1083.

meets the *Loving* prongs. However, even if she had attempted to do so, I would not be able to find on the present record that C.N.'s AD (which I *have* found was already in existence as of the day of the May 2013 vaccinations) was worsened thereafter. At best, the record supports the determination that his AD was only first manifesting the day of the May 29th vaccinations, and thus literally became "worse" thereafter, in clinical terms, as time progressed, and thus arguably the first three *Loving* prongs could be met. But Petitioner's causation theory does not at all establish that vaccines could worsen an existing case of AD, or how. Nor does the record establish *vaccine-induced* worsening, as opposed to a progression that would be expected for any child with severe AD (*Loving* prong five).

IV. This Case Was Reasonably Resolved Without a Hearing

I have opted to resolve this case on the existing record, and without holding a hearing, in accordance with my discretion. Although the parties' briefing was silent on the propriety of this determination, I shall explain my reasoning in choosing to decide the case on the papers alone.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes without a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

Here, and despite the number of expert report "rounds," the matter was reasonably decided on the papers. C.N.'s condition is not in dispute, and the medical records are straightforward in identifying his course (even if the parties dispute the significance of pre-vaccination symptoms). Dr. Bellanti's reports were concise, and his theory easy to understand—its deficiencies arose from its lack of sufficient substantiation, not from its clarity or plausibility, and evaluation of the theory could be performed without the aid of live testimony. The record (which included many items of literature) provided what was needed to decide the case.

CONCLUSION

For the aforementioned reasons, this claim is dismissed. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this Decision.[17]

IT IS SO ORDERED.

s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[17] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.